

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	Cynthia T. Clague et al.	Examiner:	Pavitra Kotini
Serial No.:	10/694,037	Group Art Unit:	3731
Filed:	October 27, 2003	Docket No.:	M190.242.101/P11210.00
Title:	METHOD AND APPARATUS FOR MAKING PRECISE INCISIONS IN BODY VESSELS		

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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This pre-appeal brief is being submitted along with a Notice of Appeal in response to the Office Action mailed December 11, 2008. Claims 7-14, 24-31, and 35-46 have been withdrawn from consideration. The pending claims 1-6, 15-23, and 32-34 were rejected. Claims 1-6, 15-23, and 32-34 remain pending in the application and are presented for reconsideration and allowance.

**The Rejection of Shapiro in view of Taylor ('108)**

Claims 1-3 and 18-20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro US Patent No. 5,314,440 in view of Taylor et al. US Patent No. 6,387,108. This rejection includes independent claims 1 and 18. Claims 2-6 and 15-17 depend from independent claim 1, and claims 19-24 and 32-34 depend from independent claim 18.

Applicants agree with the Office Action that Shapiro does not disclose the claimed features of “the fixed cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending fixed cutting blade, and wherein the blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, wherein the major portion extends generally perpendicular to the proximal trailing side” as set forth in the Office Action on page 4 (paragraph 9) and as required in independent claims 1 and 18. Applicants traverse that Taylor teaches or makes obvious these features in the claim.

For example, Taylor does not teach or make obvious the above-quoted claim features missing from Shapiro including “the fixed cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending fixed cutting blade.” Taylor

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does not include a fixed cutting blade together with a movable cutting blade, and there is no fixed cutting blade in the cited Taylor figure 6b. The device of Taylor also shows a fixed blade stop, which is blunt, rather than a “cutting edge,” at reference numeral 16 in Figures 5 and states “the cutting edge 14 engages the blade stop 16” at column 5, line 56 and column 6, line 11. Figure 6b also shows the “blade stop 16 has an upper surface 17 at the terminal end of the instrument having a groove 17a” at column 5, lines 58-59.

Additionally, Taylor does not include the above-quoted claim features missing from Shapiro including “generally straight along the direction of the laterally extending fixed cutting blade.” The upper surface 17 of the blade stop 16 is hooked in shape, and is not straight. The cutting edge 14 and the blade stop 16 include “a complementary shape” (See, column 5, lines 53-57). The cutting edge in such a device is not straight in a lateral direction but usually pointed or curved to gradually cut the tissue rather than abruptly cutting the tissue. A straight cutting edge used in the device of Taylor is undesirable because it can often tear the tissue with an abrupt cut. The gradual cutting of tissue, such as starting with a convexly-curved cutting edge, gradually cuts tissue and greatly reduces the risk of tearing.

The device taught in Taylor also suffers from the issues present in any hook-shaped penetration mechanism. That is, if the surgeon catches the point on the inside of the lumen prior to the lateral stop reaching the entrance puncture, the surgeon can be fooled into thinking the stop is against the entrance puncture. This mistake can occur quite frequently, and is made especially more likely when used on a beating heart. In this case, the opening would be too small.

The prior art also does not suggest a modification to Shapiro or to Taylor to obtain the features of the present claims. Shapiro and Taylor, as well as the device disclosed in the present application concern themselves with making an incision in the vessel with a precise length. Shapiro and Taylor do not recognize the need for providing penetration of the vessel at a constant thickness during insertion of the fixed portion into the vessel. Each of Shapiro and Taylor teach a device where the thickness of the incision during penetration with the tip of the fixed portion expands as the fixed portion is moved laterally into the vessel (See figures 6a and 6b in Taylor where the blade stop gets progressively thicker further away from

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the point 11). Neither of these references recognizes the problem Applicants address in the present application.

Because at least the above-quoted features of independent claims 1 and 18 are missing from each of Shapiro and Taylor, they would be missing from any proposed combination of the reference. Applicants submit that the independent claims are patentably distinguishable over the combination of Shapiro and Taylor. Further, dependent claims 2-6, 15-17, 19-24, and 32-34 serve to further define the patentable dependent claims and are also patentable over the combination of Shapiro and Taylor by virtue of their dependency. Applicants request removal of the rejection based on the combination of Shapiro and Taylor and also request allowance of the claims.

**The Rejection of Shapiro in view of Taylor ('108) and further in view of Taylor ('641)**

Claims 4-6, 15-17, 21-23 and 32-34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro US Patent No. 5,314,440 in view of Taylor et al. US Patent No. 6,387,108 as applied to independent claims 1 and 18 above and further in view of the Taylor et al. US Patent No. 6,036,641.

As discussed above, any proposed combination of Shapiro and Taylor ('108) will not teach all of the limitations of the claims, particularly the features of "the fixed cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending fixed cutting blade, and wherein the blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, wherein the major portion extends generally perpendicular to the proximal trailing side." Taylor ('641) teaches a device for stabilizing surgical instruments against a beating heart. Taylor does not teach or make obvious anything about a cutter configured as set forth in the claims. Thus, because the above quoted claimed features are not taught or made obvious in the prior art references of Shapiro, Taylor ('108), or Taylor ('641), the features would be missing from any proposed combination of the three references. Thus, Applicants respectfully request removal of the rejections of claims 4-6, 15-17, 21-23, and 32-34 based on the combination of Shapiro, Taylor ('108), and Taylor ('641) and also request allowance of these claims.

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**CONCLUSION**

In view of the above, Applicant respectfully submits that pending claims 1-6, 15-23, and 32-34 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-6, 15-23, and 32-34 are respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Rudolph P. Hofmann at Telephone No. (612) 573-2010, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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Respectfully submitted,

Cynthia T. Clague et al.,

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Date: March 11, 2009

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